10. Summary of Safety and Effectiveness – "510 (k) Summary"

A. Submitter Information

JUL 11 2008

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Date Prepared: January 11, 2008

B. Device Identification

Classification Name: Arthroscope and Accessories

Common Usual Name: Arthroscopic Pump

Proprietary Name: SOPRO 670 Arthroscopic Pump

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
Future Medical Systems FMS DUO	Future Medical Systems	K954465	Nov. 9, 1995

The SOPRO 670 Arthroscopic Pump is substantially equivalent to the arthroscopic pump functions of the predicate device by Future Medical Systems, arthroscopic pump and shaver model FMS DUO (K954465) previously cleared by the FDA and currently marketed.

D. Device Description

The SOPR0 670 irrigation pump is a peristaltic pump system designed to automatically provide and control distension and irrigation of the operative site during arthroscopic procedures and fluid irrigation of the operative site during laparoscopic procedures using sterile fluids. The pump is used in conjunction with specific tubing sets designed for arthroscopic procedures.

The Arthroscopy Pump SOPRO 670 is a microprocessor controlled pump system designed to provide liquid distension and irrigation of joint cavities and aspiration of liquids out of the joint cavities during diagnostic and operative arthroscopy. The Arthroscopy SOPRO 670 consists of the following main components: housing, power supply, roller wheel, pump head, a servo-motor, various setting keys and display elements. The device is to be used with special designed irrigation and suction tubings and a foot-remote control. A constant performed redundant pressure measurement controls the conformity of the actual pressure in the joint cavity with the pre-set nominal pressure.

E. Intended Use

The SOPRO 670 irrigation pump is an arthroscopic pump system intended to provide fluid distension and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures that may only be used by qualified physicians.

F. Substantial Equivalence

The SOPRO 670 is substantially equivalent to the Arthroscopic pump functions of the predicate device by Future Medical Systems, Arthroscopy Pump and Shaver Model FMS DUO (K954465) previously cleared by the FDA and currently marketed. Both the Arthroscopy Pump SOPRO 670 and the predicate device are intended to provide fluid distension and irrigation of knee, shoulder, elbow, hip, ankle and wrist joint cavities during diagnostic and operative arthroscopic procedures.
Furthermore, the Arthroscopy Pump SOPRO 670 and the predicate device FMS DUO (K954465) are both intended to provide fluid suction during arthroscopic procedures.
In addition, the device described in this notification is similar in design and technical characteristics to the Arthroscopic pump of the predicate device.

Differences that exist between the devices relating to technical specifications, performances and intended use are minor and do not affect the safety and effectiveness of the SOPRO 670 Arthroscopic Pump.

G. Performance Data

The device complies with the International Standard IEC 601-1 (Electrical Safety) .In addition, the device meets the requirements of the Underwriter Laboratories Standard UL60601-1 and bears the CE mark in accordance with the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Steve Salesky
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Mt. Laurel, New Jersey 08054

JUL 11 2008

Re: K080122
Trade/Device Name: SOPRP 670 Arthroscopic Pump
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: June 6, 2008
Received: June 9, 2008

Dear Mr. Salesky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080122

Indications for Use

510(k) Number: _____

Device Name: **SOPRO 670 Arthroscopic Pump**

Indications for Use:

The SOPRO 670 irrigation pump is a arthroscopic pump system intended to provide fluid distension and irrigation of knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures that may only be used by qualified physicians

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080122